

JUL 30 2007

**5. 510(k) SUMMARY**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The Assigned 510(k) number is K070929.

**Submitter's Identification:**

ACON Laboratories, Inc.  
4108 Sorrento Valley Boulevard  
San Diego, California 92121

Tel.: 858-875-8028  
Fax: 858-875-8099

Date Prepared: June 27, 2007

**Contact Person:**

Jinn-nan Lin, Ph.D.  
V.P., Regulatory Affairs

**Proprietary Name of the Device:**

ACON™ U120 Urine Analyzer

**Common Name:**

Urine Chemistry Analyzer

**Regulation Section and Classification:**

21 CFR § 862.2900	Automated Urinalysis System
21 CFR § 862.1340	Urinary Glucose (Non-Quantitative) Test System
21 CFR § 862.1115	Urinary Bilirubin and its Conjugates (Non-Quantitative) Test System
21 CFR § 862.1435	Ketones (Non-Quantitative) Test System
21 CFR § 864.6550	Occult Blood Test
21 CFR § 862.1550	Urinary pH (Non-Quantitative) Test System
21 CFR § 862.1645	Urinary Protein or Albumin (Non-Quantitative) Test System

21 CFR § 862.1785 Urinary Urobilinogen (Non-Quantitative) Test System  
21 CFR § 862.1510 Nitrite (Non-Quantitative) Test System  
21 CFR § 864.7675 Leukocyte Peroxidase Test  
21 CFR § 862.1095 Ascorbic Acid Test System

Class I: Automated Urinalysis System; Urinary Leukocytes, Urinary pH, Nitrite, Urinary Protein, Ketones, Urinary Urobilinogen, Urinary Bilirubin, Specific Gravity and Ascorbic Acid

Class II: Urinary Glucose and Occult Blood

**Product Code:**

KQO	Automated Urinalysis System
JIL	Urinary Glucose (non-quant.) test system
JIO	Blood, Occult, Colorimetric, in urine
LJX	Test, Urine Leukocyte
CEN	Urinary, pH (non-quant.)
JMT	Nitrite (urinary, non-quant.) test system
JIR	Protein or Albumin (urinary, non-quant.) test system
JIN	Ketones (urinary, non-quant.) test system
CDM	Urinary Urobilinogen (non-quant.) test system
JJB	Urinary Bilirubin & its conjugates (urinary, non-quant.) test system
JMA	Acid, Ascorbic, 2, 4-Dinitrophenylhydrazine (Spectrophotometric)

**Medical Specialty:**

Clinical Chemistry

**Predicate Device:**

Bayer Clinitek Status Urine Chemistry Analyzer  
Bayer Healthcare, LLC, marketed by Bayer Healthcare, LLC, located at Medfield, MA 02052, USA.  
510(k) Number: K031947

**Description:**

The U120 Urine Analyzer is a reflectance photometer that analyzes the intensity and color of light reflected from the reagent areas of a urinalysis reagent strip. Without a urine analyzer, operators must visually compare the reagent areas of the strip to a color chart using the naked eye. Obviously, visual determination for urinalysis is a time

consuming task and is prone to inaccuracy due to human misinterpretation and variable light sources. To minimize the variability associated with visual testing, the ACON U120 Urine Analyzer is specifically designed for improved accuracy and efficiency of urinalysis featuring data management and report generation capabilities.

#### **Intended Use:**

The ACON™ U120 Urine Analyzer is intended for use in conjunction with the ACON Urinalysis Reagent Strips for the semi-quantitative detection of the following analytes in urine: Glucose, Bilirubin, Ketone (Acetoacetic Acid), Specific Gravity, pH, Blood, Protein, Urobilinogen, Leukocytes and Ascorbic Acid as well as the qualitative detection of Nitrite. The ACON Urinalysis Reagent Strips are available in different combinations of the aforementioned analytes. The instrument is intended for professional, in vitro diagnostic use only. The measurement can be used in general evaluation of health, and aids in the diagnosis and monitoring of metabolic or systemic diseases that affect kidney function, endocrine disorders and diseases or disorders of the urinary tract.

#### **Technological Characteristics:**

<b>Feature</b>	<b>Specifications</b>
Methodology	Reflectance Photometer
Detection	Photosensitive diode
Throughput	Single Test Mode: 40 tests/hour Continuous Test Mode: 120 tests/hour
Memory	Last 500 results
Strip Incubation Time	1 minute
PC Port	Standard RS232C Port (cable not included)
Printing Capabilities	Internal heat-sensitive printer (included) External printer (not included) 25 Pin Parallel External Printer Port (included)
Available Languages on Screen	English and Spanish
Ambient Operating Conditions	0-40°C (32-104°F); ≤85% Relative Humidity (non-condensing)
Optimum Operating Conditions	15-30°C (59-86°F); ≤75% Relative Humidity (non-condensing)
Power Source	220 Volts AC (±10%), 50 Hz (±1) 110 Volts AC (±10%), 60 Hz (±1) 110-230V AC, 50/60Hz
Line Leakage Current	<0.5 mA
Weight	2.6 kg (5.73 lbs)
Dimensions	27.1 (L) × 26.5 (W) × 14.8 (H) cm
Display Dimensions	10.6 (W) × 2.8 (H) cm

**Comparison to Predicate Devices:**

The ACON U120 Urine Analyzer is substantially equivalent to the Bayer Clinitek Status Urine Chemistry Analyzer, K031947.

**Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Studies were conducted in-house and in clinical setting to demonstrate the performance of the ACON U120 Urine Analyzer and that the intended user can easily operate the system and obtain urinalysis results as the predicate device.

**Laboratory Testing:**

The performance characteristics of the ACON U120 Urine Analyzer were verified by many tests including temperature flex study, humidity flex study, voltage flex study, repeatability study, readability study, electric security testing, device comparison study, configuration tests and operation tests.

**Discussion of Clinical Tests Performed:**

Clinical studies were conducted using the ACON U120 Urine Analyzer. Clinical study data are presented and clinical accuracy between the ACON U120 Urine Analyzer and Bayer Clinitek Status Urine Chemistry Analyzer per ACON clinical study protocol for U120 Urine Analyzer is compared. Study results indicate that the inexperienced intended users were able to obtain comparable testing results when using the ACON U120 Urine Analyzer and a legally marketed Bayer Clinitek Status Urine Chemistry Analyzer (K031947).

**Conclusion:**

The laboratory testing and clinical study results demonstrated that the ACON U120 Urine Analyzer is safe, accurate and easy-to-use. It is also demonstrated that the ACON U120 Urine Analyzer is substantially equivalent to the Bayer Clinitek Status Urine Chemistry Analyzer (K031947), currently sold on the U.S. market.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JUL 30 2007

Acon Laboratories, Inc.  
c/o Mr. Martin O'Connor  
Germaine Laboratories, Inc.  
4139 Gardendale Center #101  
San Antonio TX, 78229

Re: k070929

Trade/Device Name: Acon™ U120 Urine Analyzer  
Regulation Number: 21 CFR 862.1340  
Regulation Name: Urinary glucose (non-quantitative) test system  
Regulatory Class: Class II  
Product Code: JIL, JIO, LJX, JRE, CEN, JMT, JIR, JIN CDM, JJB, JMA, KQO  
Dated: May 30, 2006  
Received: June 4, 2007

Dear Mr. O'Connor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

*Jean M. Cooper, M.S., D.V.M.*

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): K070929

Device Name: ACON™ U120 Urine Analyzer

### Indications for Use:

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Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benam  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

Page 1 of   1  

K070929